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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/550,145

09/21/2005

Anne T. Bruinvels

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EXAMINER

MACFARLANE, STACEY NEE

ART UNIT

PAPER NUMBER

1649

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/550,145	<b>Applicant(s)</b> BRUINVELS, ANNE T.	
	<b>Examiner</b> STACEY MACFARLANE	<b>Art Unit</b> 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27-46 and 52 is/are pending in the application.
- 4a) Of the above claim(s) 29-33, 36, 39-43 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27, 28, 34, 35, 37, 38, 44, 45, and 52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Priority***

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed on September 21, 2005.

### ***Response to Amendment***

2. Claims 27-46 and 52 are pending in the instant application.

Claims 29-33, 36, 39-43 and 46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper filed on June 20, 2007.

Claims 27, 28, 34, 35, 37, 38, 44, 45, and 52, in so far as they are drawn to the instantly-elected deramciclane or N-desmethyl-deramciclane, are under examination in the instant Office Action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on December 6, 2007 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 27, 28, 34, 35, 37, 38, 44, 45 and 52 stand rejected under 35 U.S.C.

103(a) as being unpatentable over US Patent 6,589,996, filed March 16, 2001 and

published December 6, 2001 ('996 Patent), and further in view of Meltzer HY, *The Role of Serotonin in Antipsychotic Drug Action*, Neuropsychopharmacology 21(2S): 106S-115S, August 1999.

8. On pages 12-14 of Remarks filed December 6, 2007, Applicants traverse the rejection on the grounds that Meltzer teaches the administration of deramciclanc to treat "serotonergic disorders, such as depression and anxiety", but does not teach negative symptoms of schizophrenia, as claimed, and stress the importance of the method for the treatment of suicidality. Applicants assert that there is no indication within the prior art reference that schizophrenia is a serotonergic disorder. Furthermore, Applicants argue that the Meltzer reference teaches away from the use of 5HT<sub>2C</sub> receptor antagonists as they may be counterproductive to the antagonistic effect on the 5HT<sub>2A</sub>

receptor. While these arguments have been fully considered, they are not found persuasive to overcome the rejection for the following reasons.

The claims are drawn to a method for the treatment of a patient suffering from symptoms associated with the instantly-elected negative symptoms of schizophrenia wherein that method comprises the administration of a compound having a relative 5-HT<sub>2C</sub> affinity of  $\geq 1.80$  with the proviso that the compound is other than ritanserin, clozapine, fluperlapine, loxapine, ORG-5222, pipamperone, sertindole, olanzapine, zotepine or ziprasidone, and wherein the compound is the instantly-elected deramciclane or N-desmethylderamciclane. The instant specification lacks an explicit definition for “negative symptoms” but discloses several examples of such symptoms as including cognitive symptoms explicitly taught by the reference (see previous Office Action), as well as “suicidality”. In Remarks filed December 6, 2007, Applicants stress the particular importance of the method as a treatment of suicidality (page 12), which the instant specification states, “may result from the episodes of depression to which these patients are prone” (paragraph 0060). Applicants concede that the Meltzer prior art teaches deramciclane “to treat serotonergic disorders, such as depression” (page 12) and that the Meltzer reference teaches 5-HT<sub>2C</sub> antagonists are “more effective in decreasing negative symptoms than haloperidol” (page 13). Thus, the Examiner maintains that since the '996 Meltzer Patent teaches treatment of depression with deramciclane, and the instant specification indicates that depression contributes strongly to the negative symptom of suicidality, then the prior art renders obvious the method as claimed. That the Meltzer reference suggests that 5-HT<sub>2A</sub> receptor

antagonism may have a stronger effect than 5HT2C antagonism is moot. The Meltzer reference explicitly teaches that 5-HT2C antagonists are "effective in decreasing negative symptoms", and the instant claims are silent on requirements of the method of treatment relative to the effects of 5-HT2A antagonists. Instant claims merely require the compound of administration as having a relative 5-HT2C affinity of  $> 1.80$ , and that the compound is the instantly-elected deramciclone. Thus, the instant method stands rejected as obvious over the teachings of the prior art.

### ***Conclusion***

9. No Claim is allowed.

10. This application contains claims drawn to an invention nonelected with traverse in Paper filed on June 20, 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M,W and ALT. F 6 am to 3 pm, T & R 5:30 am - 4 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane  
Examiner  
Art Unit 1649

/John D. Ulm/

Primary Examiner, Art Unit 1649